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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,679	11/05/2001	Russell Michael Hagan	2801-0165P	4024

2292 7590 02/09/2005

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ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 02/09/2005

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/985,679
Filing Date: November 05, 2001
Appellant(s): HAGAN ET AL.

Gerald M. Murphy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 18, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is essentially correct. It is noted claims 1, 3-9, 11-19, and 25 were rejected over US 6,326,383 (the parent application) for double patenting in the office action mailed April 5, 2002, wherein the application no. was inadvertently listed as 6,323,282. In the response filed April 11, 2002, applicants recognized the typographic error, but no TD was filed. However, in the consequent second non-final rejection, the double patenting rejection was dropped without explanation. There is no reason for withdrawing the double patenting rejection on the record. Therefore, the double patenting rejections are restated in this examiner's answer.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The IDS submitted August 13, 2004 has been put in the file, but has not been considered according to 37 C.F. R. 1,97 (i).

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: whether claims 1, 3-9, 11-19, and 25 are properly rejected over claims 1-4 in US 6,326,383 for double patenting.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 2, 4-9, 11, 14, 16 and 20-25; claims 3, 12, 15 and 19; and claims 10, 13, 17 and 18 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

US Patent 6,326,383 Hagan et al December 4, 2001

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-25 are rejected under 35 U.S.C. 112 first paragraph for lack of enablement;

2. Claims 1, 3-9, 11-19, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,323,282.

3. Appellants' arguments regarding the rejections of claims 1-25 under 35 U.S.C. 112 secondary paragraph are found persuasive. Particularly, the claims are broad, but not indefinite.

These rejections are fully set forth in prior office action, mailed April 21, 2004. The double patenting rejections was set forth in the office action mailed April 5, 2002. All the rejections are reiterated below:

(11) Response to Argument

Claims 1, 3-9, 11-19 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,326,383. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in the previously issued patent are species of the instant rejected claims. Those claims in the issued patent, and those herein presented would be obvious one over the other, although not reciting the identical subject matter. Particularly, the claims herein are generic to the claims in '383.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter (i.e. NK_1 antagonists, or $5HT_3$ antagonists), which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes only the several types of NK_1 antagonists (e.g., page 2-21 herein) for use in the instant method. All types of the antagonist have their distinct chemical structural characteristics, and are not obvious each from the others. They have acquired separated status. No requirements or criteria as to the chemical structure of NK_1 antagonists are described. No other NK_1 antagonists are described (i.e., as it relates to claims 1-25). With respect to $5HT_3$ antagonists, only 3 $5HT_3$ antagonists are described (see the claims). No further guidance, direction as to the other $5HT_3$ antagonists, and their chemical structual features are described. Therefore, because one of ordinary skill in the art at the time of filing Applicant's invention cannot reasonably visualize what these other "$5HT_3$ antagonists" or "NK_1 antagonists", the written description requirements under 35 U.S.C. 112, first paragraph, are not met. See MPEP 2163. Appellants' attention is further directed to *University of Rochester v. G.D. Sealer& Co.* 69 USPQ2D 1886 (CAFC, 2004). Referring to defining a compound by its activity to a specific enzyme, the court states: "The same is not necessarily true in the chemical art more generally. Even with the three dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them,..." Defining a compound by its activity to enzymes without further information about the chemical structure of the compound would not meet the written description requirements under 35 U.S.C. 112, first paragraph.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApIs 1986) at 547, the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define those compounds useful as NK_1 antagonists, or $5HT_3$ antagonists. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of NK_1 antagonist, or $5HT_3$ antagonist examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all

NK_1 antagonists, or $5HT_3$ antagonists, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation. In the present case, applicants are claiming any compound functionally possessing the envisioned activity, by claiming those compounds falling under that functional penumbra encompassed by the functional language employed; yet fail to provide a specification that enables, or suggests those actual compounds useful to practice the invention as claimed. Absent guidance the presented claims are simply an invitation to experiment placed on those attempting to practice the instant invention as claimed.

Those functional limitations herein recited fail to provide any guidance, save those examples herein provided, to the identity of compounds envisioned, or non-envisioned, suitable to practice the invention as claimed. Absent such guidance, the claims encompass all compounds possessing the instant functionality, regardless the disclosure herein provided. Thus, the provided disclosure places the burden of undue experimentation on those attempting to practice the claimed invention. The cited decisional case law was provided to establish a test for the instant rejection, not to illustrate identical underlying scientific facts. Attention is directed to General Electric Company v. Wabash Appliance Corporation et al 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claim is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more

than outline) goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants' functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provides those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et supra*, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Response to Appellants' Arguments

Issue 1-A prima facie case of lack of enablement has been established.

Appellants argue the examiner merely lists Wands factors, fails to engage in any Wands-type analysis, and makes a conclusive statement. The arguments are not persuasive. Insofar as a prima facie case of lack of enablement has been established, it is not necessary to analyze each and every Wands factors. In fact, the examiner's analysis covers all the eight factors:

The breadth of the claims are extremely broad; "applicants are claiming any compound functionally possessing the envisioned activity, by claiming those compounds falling under that functional penumbra encompassed by the functional language employed;"

The working examples are very limited, and do not support the broad scope as claimed;

The quantity of experimentation necessary: "The instant claims read on all NK_1 antagonists, or $5HT_3$ antagonists, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention."

The amount of direction or guidance provided, "It is noted that these examples are neither exhaustive, nor define the class of compounds required."

4) the nature of the invention: the employment of NK_1 antagonists and/or $5HT_3$ antagonists.

The state of the prior art, the relative skill of those in the art and the predictability of the art: "The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity."

Issue 2 Appellants' rebuttal arguments are not convincing, NK1 antagonist.

The specification and various journal articles provide no favor to appellants' position.

The Wands Factors. Following Wands factors analysis is to address the issue raised in the appeal brief.

1. Breadth of the claims

As stated in the rejections the breadth of the claims are extremely broad, it cover any compounds that may have NK1 antagonist properties, including those not known in the art at the time the claimed invention was made. Whether there is a prior art rejections to the claimed invention is irrelevant to the issue of enablement.

2. Nature of the invention

Appellants' assertion that the claimed invention does not involve a highly unpredictable technology is incorrect. The claimed invention involves identification of those compounds suitable as NK_1 antagonists, which is deemed to be unpredictable, as recognized by the court.

3. State of the prior art.

As evidenced by the specification and various articles provided by appellants, structurally distinct compounds have been found to possess the NK_1 antagonist activity, and no unique chemical feature has been known in the art. Skilled artisans are still searching for new NK_1 antagonists.

4. The relative skill of those in the art.

There are known assay methods for identifying NK_1 antagonist. However, hunting a compound by an assay method through try and error is not a proper written description. Particularly apropos to the present application is the following statement by the Supreme Court in *Brenner v. Manson*, 833 O.G. 1349, 148 USPQ 689, 696:

"But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. '[A] patent system must be related to the world of commerce rather than to the realm of philosophy.'"

5. The predictability or unpredictability of the art

Appellants do not dispute the unpredictability, but argue "some unpredictability is allowable." That may be true in some situation but not for defining a small organic compound by its activity toward an enzyme. As recognized by the court, "The same is not necessarily true in the chemical art more generally. Even with the three dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them,..." *University of Rochester v. G.D. Sealer& Co.* 69 USPQ2D 1886 (CAFC, 2004).

6. the amount of direction or guidance provided in the application

As discussed above, an assay method does not satisfy the written description requirements for therapeutical agents, particularly those small organic compounds.

7. The quantity of the experimentation

In view of the breadth of the claims, and unpredictability of the art involved, undue experimentation is required to practice the full scope of claimed invention.

8. presence or absence of working examples

Only a limited number of NK_1 antagonists is presented, no working examples related to identifying other NK1 antagonists encompassed in the claims.

Therefore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention. The journal articles provided by appellants provide no favor to appellants' position. The articles show that new NK_1 receptor antagonists are discovered after the filing of this application, and each of such discoveries acquires a separated status in the art. It is apparent that the art related to NK_1 receptor is developing and is not in its highest level. Appellants are attempting to reach through time and capture subject matter not available at the time the claimed invention was made.

Functional Language

The examiner does not try to set a *per se* rule as to the employment of functional language in claims. However, *functional language at the point of novelty*, such as Applicants', is not proper. As to Lilly, note lack of written description is lack of enablement. Claims cannot be enabled without meeting the written description requirements.

Issue 3 *$5HT_3$ antagonists Prima facie case of Non-enablement has been established*; and Issue 4 *rebuttal arguments are not convincing, $5HT_3$ antagonist..*

The arguments against the employment of NK_1 antagonist set forth above are properly applied herein. The only difference here compared to NK_1 antagonist is that the application merely provides three compounds for $5HT_3$ antagonists without any further guidance, or direction as to other $5HT_3$ antagonists encompassed thereby.

Further, the arguments are proper for all three groups of claims since each groups use at least one of the two terms: NK_1 antagonists and $5HT_3$ antagonists.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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February 7, 2005

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